

Rejections Under 35 USC 102(e)

Claims 1-7, 9 and 13-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ohno et al., USP 5,958,453. According to the Examiner, Ohno teaches a pharmaceutical preparation in solid, powder or granular form; comprising mannitol or erythritol; comprising voglibose as an active ingredient; and further comprising as a disintegrant, low substituted hydroxypropyl cellulose at about 1-15 parts by weight based on 100 parts by weight of the composition.

Applicants respectfully traverse this rejection. Ohno does not teach applicants' claimed composition with a low-substituted hydroxypropoxyl cellulose having 5% or more by weight or more to less than 7% by weight of hydroxypropoxyl group

5 < x < 7

The present invention claims using a specific low substituted hydroxypropyl cellulose having 5% by weight or more to less than 7% by weight of hydroxypropoxyl group and sugar, for a rapidly disintegrable solid solution. The section in Ohno referred to by the Examiner as relating to low substituted hydroxypropyl cellulose (column 5, lines 14-59), discloses only a weight range for disintegrants, (of which low-substituted hydroxypropyl cellulose was mentioned as one), in the composition, and does not refer to the specific type of low-substituted hydroxypropyl cellulose claimed by applicants. Ohno makes no mention of any required percentage for the hydroxypropoxyl groups, let alone a low substituted hydroxypropyl cellulose having 5% by weight or more to less than 7% by weight of hydroxypropoxyl group. The advantages of such compositions is clearly illustrated by the test examples in the specification.

Ohno does not disclose at least one element of the claimed invention and cannot anticipate. Thus, applicants respectfully request withdrawal of this rejection under 35 USC 102(e).

Rejections Under 35 USC 103(a)

Claims 1-19 are rejected under 35 USC 103(a) as being obvious over Ohno in view of Shashoua et al., USP 5,795,909. According to the Examiner, it would have been obvious to one of ordinary skill in the art to add the active ingredients taught by Shashoua to the composition taught by Ohno to arrive at applicants' invention, because, Ohno teaches all the elements of each of the claims except for some specific active ingredients, and Shashoua teaches pharmaceutical compositions in tablet form with the other claimed active ingredients.

Applicants respectfully traverse this rejection. As discussed above, even assuming, *arguendo*, that there was motivation to combine the two references, applicants' invention would still not be achieved, because neither reference teaches, nor suggests in any way, alone or in combination, the required element of a low substituted hydroxypropyl cellulose (L-HPC) having 5% by weight or more to less than 7% by weight of hydroxypropoxyl group in the

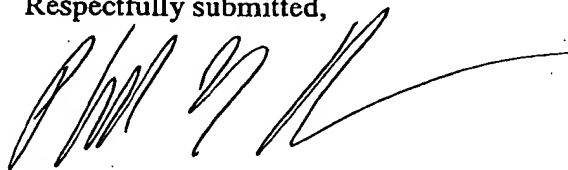
composition.

Ohno alone cannot render obvious applicants' claimed invention because it neither teaches nor suggests in any way the claimed range of hydroxypropoxyl group in the composition. The addition of Shashoua adds nothing to an obviousness argument. Shashoua relates to DHA-taxane conjugates, and does not mention any specific solid formulations. Shashoua does not disclose applicants' claimed range of hydroxypropoxyl group (and indeed does not even disclose hydroxypropyl cellulose), and provides no additional suggestion which would motivate one of ordinary skill in the art to arrive at this specific combination. The advantages of applicants' claimed composition are discussed in the specification, and include enhanced dissolution and taste and texture properties. (See Test Examples 1 and 2, at pages 40-42 of the specification).

In order for a combination of references to render a claim unpatentable under 35 USC 103, the combined teachings of the references must teach or suggest the invention as a whole, including all limitations of the claims. Given that none of the cited references, alone or in combination, teach or suggest each element of applicants' claimed composition, nor provide any motivation for arriving at that composition, there can be no prima facie case of obviousness. Applicants thus respectfully request that this rejection under 35 USC 103(a) be withdrawn.

In view of the foregoing, it is believed that all claims are now in condition for allowance. Should the Examiner believe that a conference with applicants' attorney would advance prosecution of this application, she is invited to telephone applicant's attorney at (703) 416-5160 at any time.

Respectfully submitted,



Dated: September 13, 2000

Philippe Y. Riesen, Reg. No. 35,657
Attorney for Applicant
Customer No. 23115